UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF MICHIGAN
SOUTHERN DIVISION

PIO ZAMMIT,

Plaintiff, Case No. 05-70247

v. Hon. Gerald E. Rosen

SHIRE US, INC.,

Defendant.
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ORDER REGARDING
PLAINTIFF'S VARIOUS PENDING MOTIONS

At a session of said Court, held in
the U.S. Courthouse, Detroit, Michigan
on May 4, 2005

PRESENT: Honorable Gerald E. Rosen
United States District Judge

Plaintiff Pio Zammit, proceeding *in pro per*, has recently filed several motions in this product liability suit. For the reasons set forth briefly below, the Court denies each of this motions as lacking in merit. More generally, it appears that Plaintiff's recent submissions have been filed without sufficient heed to the standards of Fed. R. Civ. P. 11(b) and the other rules governing litigation in federal court. While the Court recognizes the difficulties faced by Plaintiff in attempting to represent himself, he nonetheless must take steps to ensure that any further filings have an adequate factual and legal basis.

First, by motion filed on April 7, 2005, Plaintiff seeks leave of the Court to join the federal Food and Drug Administration ("FDA") as a party to this suit. In support of this motion, Plaintiff notes that the FDA's approval of a drug — in this case, Adderall — may

confer immunity from liability under Michigan's product liability statute. See Mich. Comp. Laws § 600.2946(5); see also Garcia v. Wyeth-Ayerst Laboratories, 385 F.3d 961, 963-64 (6th Cir. 2004) (discussing this statutory scheme). In light of this potentially immunizing effect of FDA approval, Plaintiff argues that this federal agency should share liability with the Defendant manufacturer for approving an allegedly unsafe drug and failing to require labels that alerted consumers to the purported risks of using this drug.

Plaintiff's motion, however, fails to set forth a viable theory of recovery against the FDA. It is a familiar principle, of course, that the United States and its agencies are immune from suit except to the extent that the federal government has waived its sovereign immunity and consented to be sued. See Whittle v. United States, 7 F.3d 1259, 1262 (6th Cir. 1993). Here, the only apparent statutory means for challenging the FDA's approval of Adderall would be via the Administrative Procedure Act ("APA"), 5 U.S.C. § 701 *et seq.*, which authorizes judicial review of final agency actions. Yet, before bringing such a challenge under the APA, Plaintiff must first exhaust his administrative remedies by filing a citizen petition with the FDA, see 21 C.F.R. §§ 10.25, 10.30, and then pursuing this matter through all of the administrative steps established by the agency until a final decision is issued, see 21 C.F.R. § 10.45. It does not appear that Plaintiff has pursued any such administrative remedies, or that he otherwise has identified a final agency action that fails to meet the standards of the APA.[1] Accordingly, Plaintiff has

[1]In any event, even assuming that Plaintiff was successful in persuading the FDA to withdraw its approval of Adderall or require that additional warnings be given to users of this drug, such an after-the-fact determination would not necessarily defeat the FDA-approval-based immunity granted to a drug manufacturer under Michigan's product liability statute.

failed to identify a legal basis for joining the FDA as a party to this suit.

Next, by motion filed on March 22, 2005, Plaintiff requests that Defendant (and the FDA) be sanctioned for failing to comply with a Freedom of Information Act ("FOIA") request made by Plaintiff on January 4, 2005.[2] As noted in Defendant's response, however, Plaintiff's motion is deficient in a number of respects. First, a FOIA request is not an appropriate mechanism for seeking information from a private party such as Defendant. In any event, Defendant has agreed to construe Plaintiff's FOIA request as a request for production of documents under Fed. R. Civ. P. 34, and has promised to respond in accordance with the provisions of Rule 34. Finally, Defendant correctly observes that Plaintiff has not followed the appropriate steps for seeking sanctions under Fed. R. Civ. P. 11 — including, most significantly, serving his motion upon Defendant at least 21 days before filing it with the Court, see Fed. R. Civ. P. 11(c)(1)(A) — nor has he filed a motion to compel (much less demonstrated any non-compliance by Defendant) that might ultimately lead to the imposition of discovery sanctions under Fed. R. Civ. P. 37.[3]

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[2]Having declined to join the FDA as a party to this action, the Court readily concludes that there is no basis for sanctioning this non-party. In any event, the FOIA itself includes various remedial mechanisms by which to challenge an agency's alleged failure to properly comply with a request for information. Again, there is no indication that Plaintiff has pursued any such measures, and this Court lacks a jurisdictional basis for inquiring any further into this matter in this case.

[3]To the extent that Plaintiff seeks the imposition of sanctions against Defendant for making allegedly false or frivolous statements in its answer and affirmative defenses, the Court again agrees with Defendant that Plaintiff has failed to comply with the "safe harbor" provision of Rule 11(c)(1)(A). The Court further agrees with Defendant that Plaintiff has failed to explain how any of the statements set forth in Defendant's answer and affirmative defenses might fall short of the standards of Rule 11(b). Plaintiff's mere disagreement with Defendant's view of the case does not provide a basis for Rule 11 sanctions. Moreover, as is evident from the rulings in

Finally, by motion filed on April 15, 2005, Plaintiff seeks either a judgment on the pleadings or an award of summary judgment in his favor. The discovery phase of this case is still ongoing, however, and the Court declines to entertain any dispositive motions absent a full opportunity by both parties to develop evidentiary support for their respective positions. Accordingly, this motion is denied as premature.[4]

Before leaving this matter, the Court observes that Plaintiff has fallen into a troubling pattern of frequent filings that lack any arguable merit. The Court recognizes that Plaintiff does not have the assistance of counsel — and, indeed, the Court expressly advised Plaintiff at a recent scheduling conference that he should attempt to retain an attorney, in order to avoid precisely the problems reflected in his recent submissions. Nonetheless, the Federal Rules of Civil Procedure — and, in particular, Rule 11 — impose upon counsel and unrepresented parties alike the obligation to advance only those legal positions that "are warranted by existing law or by a nonfrivolous argument for the extension, modification, or reversal of existing law or the establishment of new law," Fed. R. Civ. P. 11(b)(2), and only those factual contentions that "have evidentiary support" or "are likely to have evidentiary support after a reasonable opportunity for further investigation or discovery," Fed. R. Civ. P. 11(b)(3). Many of Plaintiff's submissions to date have fallen well short of these standards. Accordingly, Plaintiff is strongly cautioned

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this order, Plaintiff is in a particularly poor position to "throw stones" regarding Defendant's allegedly frivolous arguments in its submissions to the Court.

[4]In addition, Plaintiff's motion does not comply with the pertinent federal and local procedural rules. The motion is unaccompanied by a supporting brief, for example, nor does Plaintiff otherwise endeavor to explain how the sheaf of materials accompanying his motion might establish (or even bear upon) the various elements of a product liability claim under Michigan law.

to ensure that any future filings in this case meet the standards of Rule 11, rest upon a tenable claim for judicial relief, and otherwise comport with the rules governing federal court litigation. Failure to heed this warning may result in the imposition of appropriate (and escalating) sanctions for each successive violation of these standards and rules.

For these reasons,

NOW, THEREFORE, IT IS HEREBY ORDERED that Plaintiff's April 7, 2005 Motion to Include the FDA as a Co-Defendant is DENIED. IT IS FURTHER ORDERED that Plaintiff's March 22, 2005 Motion for Sanctions is DENIED. Finally, IT IS FURTHER ORDERED that Plaintiff's April 15, 2005 Motion for Summary Disposition is DENIED as premature, but without prejudice to Plaintiff's opportunity to advance the same or similar arguments — subject, of course, to the applicable standards and rules — in a dispositive motion filed at the conclusion of discovery.

s/Gerald E. Rosen
Gerald E. Rosen
United States District Judge

Dated: May 4, 2005

I hereby certify that a copy of the foregoing document was served upon counsel of record on May 4, 2005, by electronic and/or ordinary mail.

s/LaShawn R. Saulsberry
Case Manager